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Dear Sirs

**International Patent Application No. PCT/GB 03/03139**
**The Technology Partnership Plc**
**Our Ref: MJB07161WO**

In response to the Written Opinion of 4 August 2004, we wish to draw the examiner's attention to some aspects of the present invention the relevance of which, we believe, have not been fully appreciated.

With regard to the examiner's objection in paragraph 2.1 of the examination report, the examiner's logic cannot be followed. It is clear from claim 1 that in the mechanism of the present invention there are two distinct valve members. It is clear from the description that the valve members each include a seal (31, 33) and a stem or shaft portion (17, 29). The first valve is situated between the pressurised container and the metering chamber and is capable of movement against the action of a biassing member, to open the canister to allow medicament to flow into the metering chamber. The second valve comprises the stem 17 and radial seal 33 and is capable of being located in three different positions.

It appears that the examiner has identified the "cup-shaped piston member 2" of D1 as the first valve member. The examiner has not specifically identified a second valve member, but it would appear that this is formed by "discharge tube 5" and we will proceed on this basis.

It is fundamental to the current invention that the second valve has three distinct positions and that these constitute three different states in the sequence of operation corresponding to the functions of filling (or metering), dispensing and resting. The first and second valve members of D1 co-operate to enable these three functions but we do not accept that the discharge tube 5 has three distinct positions or that the valve has three corresponding distinct states. In

fact the discharge tube 5 has only two distinct positions and there are only two distinct states in the sequence of operation. Furthermore, in our opinion, it is a weakness of D1 that the dispensing function occurs whilst the apparatus is in transition (Fig 4) between two other states.

A key advantage of the valve construction of the present invention is that the first valve member can close fully long before the second valve is opened. This overcomes a problem associated with prior art devices, such as that shown in D1, namely the uncontrollable pressure balancing that takes place out of necessity between the different parts of the apparatus.

A further advantage of the construction of the present invention is that the distinct closure position of the first valve ensures a well-defined metering volume. In contrast, the metering volume of D1 changes in volume as the member 2 is moved through the metering chamber 1. This is very undesirable as the examiner will appreciate.

We therefore maintain that claim 1 as presently drafted is both novel and inventive over the prior art cited by the examiner.

In view of the foregoing, we also believe that the examiner's objections based on the dependent claims 7, 10 and 12 are moot.

However, for the sake of completeness and in connection with claim 7, we note that the examiner states that he believes that D1 discloses a face seal. Within the meaning of the present invention, and in accordance with conventional terminology, a face seal co-operates with a valve seat. The seal is formed as the valve member is compressed against the valve seat. The specification on page 6, lines 22 to 35 sets out this meaning of the term. It is not clear what part of the inhaler disclosed in D1 is construed by the examiner to be a face seal. In fact, at column 2, lines 40 to 45 of D1 it is stated that the "sealing ring 4 acts as a valve in conjunction with the cup-shaped piston member 2" thereby providing a sliding seal. Evidently therefore, D1 does not disclose a face seal and we believe that claim 7 is novel in view of the disclosure of D1.

We are interested to note the examiner's conclusion that claims 13 and 14 are novel and inventive. The examiner notes that the method results in metering chambers of different volumes. The inventive feature is therefore apparent as the direct product of the process of manufacturing the inhaler. Therefore any inhaler made by this method and including this feature would be covered by claims 13 and 14. However, such inhalers are defined in claim 12 having valve mechanisms in

accordance with claims 1 and 12 and therefore the disparity in the examiner's findings with regard to those claims is not understood.

We look forward to receiving a favourable IPER in due course.

Yours faithfully
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